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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/050,219	01/14/2002	Rangarajan Sundar	P905 US	6395

28390 7590 11/15/2005

MEDTRONIC VASCULAR, INC.
IP LEGAL DEPARTMENT
3576 UNOCAL PLACE
SANTA ROSA, CA 95403

EXAMINER	
CAMERON, ERMA C	

ART UNIT	PAPER NUMBER
1762	

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/050,219	SUNDAR, RANGARAJAN	
	Examiner	Art Unit	
	Erma Cameron	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *1-16,29 and 30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claim 25 is objected to because of the following informalities: typo. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 17-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

"...around its longitudinal axis..." in claim 17 is new matter. The examiner cannot find where in the specification as originally filed it is stated that the rotation is about the longitudinal axis.

4. Claims 17-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method wherein the stent is rotated during immersion at 100-3500 RPM and at 600-25000 during withdrawal, does not reasonably provide enablement for any speed of rotation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and sue the invention commensurate in scope with these claims.

It appears that fairly high speeds are needed in the claimed invention. For instance, it appears that a rotation speed of 1 RPM during immersion and during withdrawal would not produce the desired results.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 17-22 and 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy (6555157).

'157 teaches immersing a stent in a coating liquid, and then centrifuging it, with its longitudinal axis parallel to the axis of rotation, at speeds like 6500 RPM (3:32-55; 6:46-61; 7:9-17; see the Example). Multiple coats may be formed (9:66-10:3). It is the examiner's

position that if the stent were rotated even slightly during the immersion that '157 would meet the limitations of claim17. The centrifuge is controlled by a motor (6:46-61), thus meeting claim 28.

Regarding the rate of immersion and withdrawal and the immersion time, as well as the thickness of the coating, '157 is silent on these aspects of the process. It would have been obvious to one of ordinary skill in the art to have optimized these parameters through no more than routine experimentation, as they are known to be important and controllable parameters in a coating process.

Rotation forcing the coating to an outer portion (claim 18), immersion controlling the wetting characteristics (claim 20) and controlling thickness during withdrawing (claim 24) are inherent in the '157 process.

7. Claims 17-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/52772.

'772 teaches applying a coating to a stent by immersion and using rotation about the longitudinal axis at 100-100000 RPM to distribute the coating (see Abstract; 4:18-30; 12:19-29; 13:1-10; 14:14-21. The rotation is done by a driving member, thus meeting claim 28 (6:26-7:7) It appears that the rotation occurs during immersion as well as after withdrawal (see Example 2). In addition, it is the examiner's position that if the stent were rotated even slightly during the immersion that '772 would meet the limitations of claim 17.

Regarding the rate of immersion and withdrawal and the immersion time, as well as the thickness of the coating, '772 is silent on these aspects of the process. It would have been obvious to one of ordinary skill in the art to have optimized these parameters through no more than routine experimentation, as they are known to be important and controllable parameters in a coating process.

Rotation forcing the coating to an outer portion (claim 18), immersion controlling the wetting characteristics (claim 20) and controlling thickness during withdrawing (claim 24) are inherent in the '772 process.

Regarding the multiple coatings of claim 19, adding additional coats would merely be a variation on the process.

8. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy (6555157) taken in view of WO 01/52772.

'157 is applied here for the reason given above.

'157 does not teach that the rotation speed during immersion is 100-3500 RPM.

'772 teaches that rotation is carried out during immersion at 100-100000 RPM (see Abstract, Example 2).

It would have been obvious to one of ordinary skill in the art to have added the rotation-during-immersion process of '772 to the '157 process because of the teaching that the '772 rotation process produces a predictable coating (see Abstract).

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 17-28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-20 and 22-23 of copending Application No. 10/413827. Although the conflicting claims are not identical, they are not patentably distinct from each other because '827 claims a surface roughness that should overlap with the roughness achieved by the process of the instant application, because the processes are very similar. In addition, the immersion and withdrawal rates overlap.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Erma Cameron whose telephone number is 571-272-1416. The examiner can normally be reached on 8:30-6:00, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Erma Cameron

ERMA CAMERON
PRIMARY EXAMINER

Erma Cameron
Primary Examiner
Art Unit 1762

November 13, 2005